

Serial Number 09/839,366

REMARKS

Applicant has amended the claims in order to more particularly define the invention taking into consideration the outstanding Official Action. Claim 11 has been amended to correct an obvious typographical error in its dependency as this claim should have been dependent upon claim 10 as it is not proper for a dependent claim to be dependent upon itself. The present amendment corrects this error.

In addition, claim 20 has been amended to further specify the value xCH which is a homeopathic dilution and this amendment is fully supported by Applicant's specification. Applicant most respectfully submits that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The rejection of claims 1-22 under 35 U.S.C. 101 because the claimed invention, setting forth an incredible utility, lacks patentable utility. This rejection having been carefully considered is most respectfully traversed.

It is urged in the Official Action that Applicant has supplied only anecdotal evidence for the claimed subject matter. The Examiner refers to two prior art references which is urged employs the same manner of therapy. This is specifically traversed in view of the results achieved by the presently claimed invention and as described in the working examples. While Applicant appreciates the Examiner's comments that one of ordinary skill in the art would view a randomized, double-blind, placebo-controlled clinical trial more convincing than anecdotal accounts related by Applicant, this is not the standard for a lack of utility rejection under 35 U.S.C. 101. This is especially true in view of the fact that the Examiner relies upon references from the prior art to reject claims over the prior art. These references clearly establish the utility of the claimed invention along with the experimentation described in Applicant's specification. The impropriety of the rejection under 35 U.S.C. 101 has been established and should be withdrawn.

As noted by the Examiner, the application contains clinical evidence as set forth in the Examples which provide effective results for the presently claimed invention.

Serial Number 09/839,366

Moreover, the French patent which corresponds to the present application's parent has issued as a patent further evidencing that individuals of skill in the art would appreciate that the claimed invention does not have an incredible utility requiring the submission of double-blind tests. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicant notes the objection to the specification under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and use the invention and thereby failing to provide an enabling disclosure. Applicant has noted the *In re Wands* Decision and believe that the present specification complies with the requirements of this Decision as would be appreciated by one of ordinary skill in the art. The present application contains a detailed discussion of the invention along with working Examples including clinical studies by Applicant. Clearly, based upon the disclosure of the specific types of treatments employed, including the concentration and the active ingredient treated, one of ordinary skill in the art would clearly be able to perform the invention without undue experimentation. Accordingly, it is most respectfully requested that the objection to the specification be withdrawn.

Applicant has carefully considered the rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification. It is noted that this rejection does not apply to claim 12 which has not been rejected under 35 U.S.C. 112. Claim 12 deals with the method of claim 1 wherein the active principle to be eliminated is a virus or a viral particle. Thus, the specification is fully enabling in this regard.

Applicant most respectfully submits that for similar reasons, the specification is fully enabling for all of the claims in the application. However, the independent claims are further restricted and the scope of the claims must be taken into consideration in evaluating the efficiency of the disclosure. For example, claim 2 further specifies that the effect of the elimination of a mineral compound is to restore normal function to an ion channel. Moreover, claim 19 provides that the mineral compound is a potassium, calcium or antimony containing mineral compound as does claim 20. Further, claim 20 is further specific in defining the value of x as 4, 5, 7, 15 or 30. Turning to the working

Serial Number 09/839,366

examples set forth in the present application, it may be seen that one of ordinary skill in the art would certainly find the specification enabling with no more than routine experimentation. Accordingly, it is most respectfully requested that this rejection be withdrawn and if not withdrawn, clarified with respect to the specific claims and why one of ordinary skill in the art would not find a disclosure for the more limiting aspects of the invention as set forth in the claims and as discussed above.

The rejection of claims 1-11, 13-19 and 20-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention has been carefully considered but is most respectfully traversed. Applicant again notes that claim 12 is not included in this rejection and therefore claim 12 is in full compliance with 35 U.S.C. 112.

The Examiner urges that the claims are indefinite by the phrase "active principle, R" or, those compounds that are poisons or part of a poison and thereby failing to clearly set forth the metes and bounds of the patent protection desired. However, Applicant refers to the prior art relied upon by the Examiner in the prior art rejection and also the level of skill of one of ordinary skill in the art to which the invention pertains. The clear meaning of the term is discernible to one of ordinary skill in the art, especially from a reading of the specification. Moreover, the terms referred to in the rejection only appear in the main claims and the further limited claims do not seem to have been taken into consideration. Compounds which are poisons or parts of poisons would be known to one of ordinary skill in the art to which the invention pertains. Clarification of the rejection if it is maintained with respect to the dependent claims would be appreciated in the next Official Action to clarify the issues to proceed with an Appeal should an Appeal prove necessary.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Labrecque et al., Tetau and Applicant's admission on the record, and all of record has been carefully considered but is most respectfully traversed. Applicant has not received a copy of the references which were cited in the parent application.

Applicant wishes to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states

Serial Number 09/839,366

that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

It is urged in the Official Action that claims 1-22 and the primary reference differ as to the metal ion employed and the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regime. The first deficiency is said to be cured by Tetau teaching employment of divalent metal ions to effect the desired therapeutic goals. However, there is no specificity in the Official action as to where in Tetau these teachings are present and to which divalent metal ions in the claims as applied. For example, where is there any teaching concerning restoration of normal function to the perturbed pericellular transport system as required by claim 1? Similarly, where is the teaching with respect to the specific dilutions set forth in claims 9, 11 and 18? These are specific claim limitations which cannot be ignored. Applicant wishes to emphasize that obvious to try is not the standard of obviousness under 35 U.S.C. 103 and that

Serial Number 09/839,366

Applicant's specification may not be used as a teaching reference to provide the necessary motivation to modify the prior art and arrive at the claimed invention. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Cazin et al., Besnouin and Applicant's admission of record has been carefully considered but is most respectfully traversed.

The Official Action urges that Cazin et al. and Besnouin teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically arsenic compounds. It is further urged that these medicaments are taught as useful for producing the retention of, or causing excretion of compounds responsible for disease. It is then urged in the Official Action that the skilled artisan would have expected compounds residing in the same chemical period to possess therapeutically equivalent effects. However, there is no support in the Official Action to establish this equivalency. Therefore, this aspect of the rejection is most respectfully traversed.

The second deficiency is said to be cured by Applicant's admission that the xCH factor effects the therapy in a similar and predictable manner but this is based upon Applicant's teaching which is not available as prior art and a rejection based upon such disclosure should be withdrawn. It is then urged that the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy regardless of etiology. However, this is a conclusion without factual basis and clarification as to the basis of this conclusion is requested if the rejection is not withdrawn so that the issues may be clear for appeal. Clearly, this is based upon the teachings in Applicant's specification which may not be used as a teaching reference to provide the missing motivation to modify the prior art to overcome the deficiencies in the prior art. Otherwise, the rejection applies an obvious to try standard which is not the standard of obviousness under 35 USC 103. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Serial Number 09/839,366

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By Richard E. Fichter

Richard E. Fichter

Registration No. 26,382

625 Slaters Lane - 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500

REF:kdd
A01.wpd

March 18, 2002

Serial Number 09/839,366

Marked-Up Version Showing Changes Made**IN THE CLAIMS:**

Please replace claim 11 with amended claim 11 as follows:

11(Amended). The method of claim [11] 10, wherein x is 4, 5, 7, 15 or 30 and the active principle to be eliminated is a poison or part of a poison.

Please replace claim 20 the following amended claim 20.

20(Amended). The method of claim 2, wherein R is a mineral compound which is a potassium, calcium or antimony containing mineral compound, and x is 4, 5, 7, 15 or 30.